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10/568,705	08/10/2006	Murray Frederick Broom	061967-0103	4849

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EXAMINER

BHAT, NARAYAN KAMESHWAR

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1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,705	Applicant(s) BROOM, MURRAY FREDERICK	
	Examiner NARAYAN K. BHAT	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-68 is/are pending in the application.
- 4a) Of the above claim(s) 56-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 43-68 are pending in this application.

Election/Restrictions

2. Applicant's election of group I, claims 43-55 in the reply filed on July 25, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claim 56-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of group II there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 25, 2008.
4. Claims 43-55 are under prosecution.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 43, 48-52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Niermann et al (USPN 5,919,420 issued Jul. 6, 1999).

Regarding claim 43, Niermann et al teaches a method of collecting a sample from a material comprising a device containing a ball and socket for sample collection.

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Niermann et al further teaches a chamber shaped at one end to form a socket (Fig. 1, # 40, column 4, lines 14-250 and at the other end to form a sample collection reservoir (Fig. 1, Sample collection reservoir # 130, column 3, lines 47-67 and column 4, lines 1-13). Niermann et al also teaches a ball housed within the socket, wherein at least part of an external surface of the ball in the socket is configured to contact the sample (Fig. 2, Figs. 3 and 4, Ball # 20, External surface of the ball # 43, Socket # 40, column 2, lines 5-24, column 4, lines 26-67 and column 5, lines 1-5, step 'a' of the instant claim).

Niermann et al also teaches introducing material, i.e., blood on the surface to the device (Fig. 2 and column 6, lines 64-65, column 8, lines 26-30, step 'b' of the instant claim) and rotating the ball on the said surface (Abstract, column 2, lines 5-24, column 8, 23-30, step 'c' of the instant claim) and collecting the sample in the collection reservoir (Abstract, column 2, lines 5-24, column 8, lines 16-45, step'd' of the instant claim).

Regarding claim 48, Niermann et al teaches that the sample passes from the collection reservoir (Fig. 2, # 130) through an outlet (Fig. 2, # 115, column 4, lines 4-13). Niermann et al also teaches passing of sample from collection reservoir to clinical analyzer via automated sample probe (column 4, lines 7-9) is reasonably interpreted as an outlet as described in the instant specification (Instant specification, USPGPUB, paragraph 0063).

Regarding claim 49, Niermann et al teaches that collection tube, i.e., conduit (Fig. 2, # 100) connected to the outlet (Fig. 2, # 115, column 3, lines 64-67, and column 4, lines 1-4). Since the instant specification does not provide the limiting definition for

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conduit, claim is broadly interpreted to include the conduit as tube as defined in the Random house unabridged dictionary.

Regarding claims 50 and 51, Niermann et al teaches the measuring the volume of the sample collected in the collection reservoir, i.e., small volume (Fig. 2, collection reservoir # 130, column 4, lines 3-6), which is reasonably interpreted as performing the analysis of the sample in collection reservoir.

Regarding claim 52, Niermann teaches that sample in the device is connected to a clinical analyzer device via automated sample probe for analysis of the sample (column 4, lines 4-13).

Regarding claim 54, Niermann teaches that the samples are blood, biological or non-biological sample (column 3, lines 51-53 and column 8, lines 43-45).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (USPN 5,919,420 issued Jul. 6, 1999) in view of Sharpe (USPN 5,554,537 issued Sep. 10, 1996).

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Claim 45 is dependent from claim 44. Claims 44, 46 and 47 are dependent from claim 43. Teachings of Niermann et al regarding claim 43 are described in this office action in section 6.

Regarding claims 44-47, Niermann et al teaches that the liquid from the liquid containing surface are transferred from the ball to the collection reservoir (column 8, lines 38-45). Niermann et al are silent about an absorbent material housed within collection reservoir and in contact with the external surface. However, absorbent material housed within a collection reservoir and in contact with the external surface were known in the art at the time of the claimed invention was made as taught by Sharpe.

Sharpe teaches a method for collecting the sample comprising a device containing an absorbent material housed within collection reservoir (Fig. 1, Absorbent material # 7, collection reservoir # 3, column 3 lines 10-15) and further teaches that the absorbent material is in contact with the external surface of the material (column 2, lines 48-62).

Regarding claim 45, Sharpe teaches that the absorbent material is absorbent filter (column 3, lines 15-20).

Regarding claim 46, Sharpe teaches applying fluid to the material prior to collecting the sample (column 2, lines 35-43).

Regarding claim 47, Sharpe teaches the suspending the sample in a fluid in the collection reservoir (column 2, lines 43-47).

Sharpe further teaches that the absorbent material retains large volumes of liquid and releases liquid when compressed and expand to reabsorb liquid when the compressive force is released to collect large amount of sample in the reservoir in suspension form for further analysis (column 2, lines 35-47 and column 5, lines 4-17).

Combined teachings of Niermann et al and Sharpe provide a method for collecting sample using a ball and socket device with an absorbent material in the reservoir to collect large amount of sample.

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the step of collecting sample of Niermann et al with absorbent material housed within the collection reservoir of Sharpe with reasonable expectation of success.

An artisan would be motivated to modify the step of collecting sample of Niermann et al with the expected benefit of having an absorbent material retaining large volumes of liquid and releasing a liquid when compressed and expanding to reabsorb liquid when the compressive force is released to collect large amount of sample in the reservoir in suspension form for further analysis as taught by Sharpe (column 2, lines 35-47 and column 5, lines 4-17), thus providing large volume of sample from the material for further analysis in the method of Niermann et al.

9. Claims 43, 50, 52-53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (USPN 5,919,420 issued Jul. 6, 1999) in view of Shuber (USPN 5,633,134 issued May 27, 1997).

Claim 53 is dependent from claim 52. Claims 52 and 55 are dependent from claim 50, which is dependent from claim 43. Teachings of Niermann et al regarding claims 43, 50 and 52 are described in this office action in section 6.

Regarding claim 53, Niermann et al teaches that the analysis device is a clinical analyzer (column 4, line 9). Niermann et al are silent about a thermocycler device.

Regarding claim 55, Niermann et al teaches that the sample comprises blood and other contaminant sample (column 8, lines 43-45) and further teaches clinical analyzer to evaluate sample (column 4, lines 4-13). Niermann et al are silent about analysis comprises evaluating substance for a DNA. However, sample analysis using thermocycler device for DNA was known in the art at the time of the claimed invention was made as taught by Shuber.

Shuber teaches a method for collecting sample comprising blood and biological fluid samples for further DNA analysis (column 2, lines 44-60). Shuber also teaches analysis comprises evaluating the substance DNA (Example 1 and column 2, lines 28-37) using a thermocycler (column 4, lines 63).

Combined teachings of Niermann et al and Shuber provide a method for collecting sample using a ball and socket device and evaluating the DNA of the sample. Shuber et al also teaches use of thermocycler provides a rapid cost effective process for simultaneously testing large number of individuals for the presence or absence of multiple mutations in one gene or multiple genes (Abstract and Example 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the analysis step of the collected

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sample of Niermann et al with DNA analysis step of Shuber with reasonable expectation of success.

An artisan would be motivated to modify the analysis step of the collected sample of Niermann et al with the expected benefit of using a thermocycler and providing a rapid cost effective process for simultaneously testing large number of individuals for the presence or absence of multiple mutations in one gene or multiple genes as taught by Shuber (Abstract and Example 2).

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Ram R. Shukla/

Supervisory Patent Examiner, Art Unit 1634